



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/426,548 | 10/22/1999 | DAVID ROBBINS | DEX-0054 | 2041 |
| 32800 | 7590 | 10/31/2005 | EXAMINER | |
| LICATA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053 | | | WOITACH, JOSEPH T | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1632 | |

DATE MAILED: 10/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**UNITED STATES DEPARTMENT OF COMMERCE****U.S. Patent and Trademark Office**

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

| | | | |
|--------------------------------|-------------|---|---------------------|
| APPLICATION NO/ CONTROL NO. | FILING DATE | FIRST NAMED INVENTOR / PATENT IN REEXAMINATION | ATTORNEY DOCKET NO. |
|--------------------------------|-------------|---|---------------------|

| |
|----------|
| EXAMINER |
|----------|

| | |
|----------|-------|
| ART UNIT | PAPER |
|----------|-------|

10262005

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

Attached is a copy of the signed and initialed IDS form originally filed March 20, 2000. It is noted that the previous copy had the Examiner's initials, but not the signature at the bottom of each page (see copy present in the electronic file).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph Woitach

F A C S I M I L E C O V E R S H E E T

Licata & Tyrrell P.C.

66 E. Main Street
Marlton, New Jersey

Tel: (856) 810-1515
Fax: (856) 810-1454

March 15, 2005

TO: Mrs. Pinkney
US Patent and Trademark Office

GROUP: 1632

FAX NUMBER: 703-308-6642

ATTORNEY DOCKET NO.: DEX-0054

SERIAL NO.: 09/426,548

FILED: October 22, 1999

NUMBER OF PAGES: 8

MESSAGE:

Dear Mrs. Pinkney:

Attached please find a copy of the Supplemental Information Disclosure Statement as filed on February 29, 2000.

Thank you, Mariana for: Kathleen A. Tyrrell, Registration No. 38,350

URGENT! PLEASE DELIVER IMMEDIATELY UPON RECEIPT. THANK YOU!

* * * * *

If you have any questions, or did not receive the proper number of pages, or had trouble during transmission, please call 856-810-1515.

CONFIDENTIALITY NOTICE

The information contained in this facsimile message is legally privileged and confidential, and intended only for the use of the individual(s) and/or entity(ies) named above. If you are not the intended recipient, you are hereby notified that any unauthorized disclosure, copying distribution or taking of any action in reliance on the contents of the telecopied materials is strictly prohibited and review by any individual other than the intended recipient shall not constitute waiver of the attorney-client privilege. If you have received this transmission in error, please immediately notify us by telephone in order to arrange for the return of the materials. Thank you.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DEX-0054
Inventors: ROBBINS ET AL.
Serial No.: 09/426,548
Filing Date: OCTOBER 22, 1999
Examiner: NOT YET ASSIGNED
Group Art Unit: 1632
Title: NOVEL MUTATIONS IN HUMAN MLH1 AND HUMAN
MSH2 GENES USEFUL IN DIAGNOSING
COLORECTAL CANCER

I, Jane Massey Licata, Registration No. 32,257, certify that this correspondence is being depositing with the U.S. Postal Service as First Class Mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

On this date: February 29, 2000

Jane Massey Licata
Jane Massey Licata, Registration No. 32,257

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

(XX) In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into

the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required.

- () In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, therefore:
 - () Certification in Accordance with §1.97(e) is set forth below; or
 - () The fee of \$240.00 as set forth in §1.17(p) is attached.
- () In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$130.00 as set forth in §1.17(i)(1).
- (XX) Copies of each of the references listed on the attached Form PTO-1449 (modified) are enclosed herewith..
- () In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 (modified) are not enclosed herewith because they were previously

submitted to the U.S. Patent and Trademark Office in prior application Serial No. _____, filed _____, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

Please charge any deficiency or credit any overpayment to Deposit Account No. 12-1086. This form is submitted in duplicate.

() The relevance of the listed references in a foreign language is as stated in the specification at pages @@.

(XX) All listed references are in the English language.

Respectfully submitted,

Jane Massey Licata

Jane Massey Licata
Registration No. 32,257

Date: February 29, 2000

Law Offices of
JANE MASSEY LICATA
66 E. Main Street
Marlton, New Jersey 08053

(856) 810-1515

Sheet 01 of 04

Form PTO-1449 Modified

List of Patents and Publications
Cited by Applicant
(Use several sheets if necessary)

U.S. Department of Commerce

Docket No.
DEX-0054

Serial No.
09/426,548

Applicant
ROBBINS ET AL.

Filing Date
OCTOBER 22, 1999

Group
1632

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| | | |
|----|----|--|
| 76 | AA | Bronner et al., "Mutation in the DNA mismatch repair gene homologue hMLH1 is associated with hereditary non-polyposis colon cancer", 1994 Nature 368; 258-261 |
| | AB | Burke et al., "Recommendations for Follow-up Care of Individuals With an Inherited Predisposition to Cancer", 1997 J. Am. Med. Assoc. 277(11) 915-919 |
| | AC | Dunlop et al., "Screening for people with a family history of colorectal cancer", 1997 314; 1779-1790 |
| | AD | Dutton et al., "Simultaneous Detection of Multiple Single-Base Alleles at a Polymorphic Site", 1999 Biotechniques 11; 700-702 |
| | AE | Fishel et al., "The Human Mutator Gene Homolog MSH2 and Its Association with Hereditary Nonpolyposis Colon Cancer", 1993 Cell 75; 1027-1038 |
| | AF | Frohman et al., "Cut, Paste and Save: New Approaches to Altering Specific Genes in Mice", 1989 Cell 56; 145-147 |
| | AG | Giardiello et al., "The Use and Interpretation of Commercial APC Gene Testing for Familial Adenomatous Polyposis", 1997 New Engl. J. Med. 336; 823-827 |
| | AH | Han et al., "Genomic structure of human mismatch repair gene, hMLH1, and its mutation analysis in patients with hereditary non-polyposis colorectal cancer (HNPCC) 1995 Human Mol. Genet. 4(2) 237-242 |
| | AI | Kohler et al., "Continuous cultures of fused cells secreting antibody of predefined specificity", 1975 Nature 256; 495-497 |

EXAMINER

DATE CONSIDERED

10/25/05

Sheet 02 of 04

| | | | |
|---|----|---|--------------------------|
| Form PTO-1449 Modified | | Docket No. DEX-0054 | Serial No. 09/426,548 |
| List of Patents and Publications Cited by Applicant (Use several sheets if necessary) | | Applicant ROBBINS ET AL. | |
| | | Filing Date OCTOBER 22, 1999 | Group 1632 |
| U.S. Department of Commerce | | | |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | |
| 76 | AJ | Kolodner et al., "Structure of the Human MLH1 Locus and Analysis of a Large Hereditary Nonpolyposis Colorectal Carcinoma Kindred for mlh1 Mutations", 1995 Cancer Research 55; 242-248 | |
| | AK | Kolodner et al., "Structure of the Human MSH2 Locus and Analysis of Two Muir-Torre Kindreds for msh2 Mutations", 1994 Genomics 24; 516-526 | |
| | AL | Leach et al., "Mutations of a mutS Homolog in Hereditary Nonpolyposis Colorectal Cancer", 1993 Cell 75;1215-1225 | |
| | AM | Liu et al., "hMSH2 Mutations in Hereditary Nonpolyposis Colorectal Cancer Kindreds" 1994 Cancer Research 54; 4590-4594 | |
| | AN | Liu et al., "Analysis of mismatch repair genes in hereditary non-polyposis colorectal cancer patients", 1996 Nature Medicine 2; 169-174 | |
| | AO | Liu et al., "Genetic instability occurs in the majority of young patients with colorectal cancer", 1995 Nature Medicine 1; 348-352 | |
| | AP | Lynch et al., "Genetics, Natural History, Tumor Spectrum, and Pathology of Hereditary Nonpolyposis Colorectal Cancer: An Updated Review", 1993 Gastroenterology 104; 1535-1549 | |
| | AQ | Mary et al., "Mutational analysis of the hMSH2 gene reveals a three base pair deletion in a family predisposed to colorectal cancer development", 1994 Human Molecular Genetics 3(11) 2067-2069 | |
| | AR | Newton et al., "Analysis of any point mutation in DNA. The amplification refractory mutation system (ARMS)", 1989 Nucleic Acids Research 17; 2503-2516 | |
| EXAMINER | | DATE CONSIDERED 10/25/05 | |

Sheet 03 of 04

| | | | |
|---|----|--|--------------------------|
| Form PTO-1449 Modified | | Docket No. DEX-0054 | Serial No. 09/426,548 |
| List of Patents and Publications Cited by Applicant (Use several sheets if necessary) | | Applicant ROBBINS ET AL. | |
| | | Filing Date OCTOBER 22, 1999 | Group 1632 |
| U.S. Department of Commerce | | | |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | |
| 76 | AS | Nicolaidēs et al., "Mutations of two PMS homologues in hereditary nonpolyposis colon cancer", 1994 Nature 371; 75-80 | |
| | AT | Nystrom-Lahti et al., "Founding mutations and Alu-mediated recombination in hereditary colon cancer", 1995 Nature Medicine 1(11); 1203-1206 | |
| | AU | Okayama et al., "Rapid, nonradioactive detection of mutations in the human genome by allele-specific amplification", 1989 J. Lab. Clin. Med. 1214; 105-113 | |
| | AV | Papadopoulos et al., "Mutation of a mutL Homolog in Hereditary Colon Cancer", 1994 Science 263; 1625-1629 | |
| | AW | Parker et al., "AmpliTag DNA Polymerase, FS Dye-Terminator Sequencing: Analysis of Peak Height Patterns", 1996 Biotechniques 21; 694-699 | |
| | AX | Sarkar et al., "Characterization of Polymerase Chain Reaction Amplification of Specific Alleles", 1990 Anal. Biochem. 186; 64-68 | |
| | AY | Sommer et al., "A Novel Method for Detecting Point Mutations for Polymorphisms and Its Application to Population Screening for Carriers of Phenylketonuria", 1989 Mayo Clin. Proc. 64; 1361-1372 | |
| | AZ | Tomlinson et al., "Germline HNPCC gene variants have little influence on the risk for sporadic colorectal cancer", 1997 J. Med. Genet. 34; 39-42 | |
| | BA | Vasen et al., "The International Collaborative Group on Hereditary Non-Polyposis Colorectal Cancer (ICG-HNPCC), 1991 34; 424-425 | |
| EXAMINER | | DATE CONSIDERED | |
| [Signature] | | 10/25/05 | |

Sheet 04 of 04

| | | | |
|--|----|--|---------------------------------|
| Form PTO-1449 Modified | | Docket No. DEX-0054 | Serial No. 09/426,548 |
| List of Patents and Publications Cited by Applicant (Use several sheets if necessary) | | Applicant ROBBINS ET AL. | |
| | | Filing Date OCTOBER 22, 1999 | Group 1632 |
| U.S. Department of Commerce | | | |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | |
| 7w | BB | Wijnen et al., "Seven New Mutations in hMSH2, an HNPCC Gene, Identified by Denaturing Gradient-Gel Electrophoresis", 1995 Am. J. Hum. Genet. 56; 1060-1066 | |
| 1 | BC | Wu et al., "Allele-specific enzymatic amplification of β -globin genomic DNA for diagnosis of sickle cell anemia", 1989 Proc. Natl. Acad. Sci. USA 86; 2757-2760 | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| EXAMINER | | DATE CONSIDERED | |
| [Signature] | | 10/25/05 | |